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Subject: Environmental Defense comments on N,N-Dimethylacetoacetamide (CAS# 2044-64-6)

(Submitted via Internet 6/22/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Jlr@cpma.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for N,N-Dimethylacetoacetamide (CAS# 2044-64-6).

The test plan and robust summaries for N,N-dimethylacetoacetamide (DMAA) were submitted by the Color Pigments Manufacturing Association. The submission was crisply and objectively written and fulfills the requirements of the HPV program. DMAA is manufactured in a closed system, according to the test plan, and it is used solely as a co-promoter in the production of unsaturated polyester resins present in coating materials. It is also used as an industrial intermediate in the synthesis of an unidentified pesticide. (We cannot help but wonder why the Color Pigments Manufacturing Association is involved in pesticide production.) No information is provided on the amount of DMAA present in the unnamed pesticide or other industrial or consumer end products so the potential for human and environmental exposures cannot be evaluated.

Existing data on some but not all SIDS endpoints are available. Data are especially lacking for the mammalian health endpoints. The sponsor proposes a number of studies to address these data gaps and we agree with all the proposals for conducting new studies. Specific comments are as follows:

1. The sponsor proposes to conduct water stability and algal toxicity studies and these proposals seem reasonable. We do note that existing fish and aquatic invertebrate toxicity data indicate that DMAA possesses a very low order of acute toxicity to the species tested, although it does appear to be resistant to biodegradation.

2. The sponsor proposes to conduct in vitro mutation and chromosomal aberration studies, as no data exist for these endpoints. While we agree with this proposal, we ask the sponsor to identify the test systems to be used in these studies.

3. There are no existing data on the repeat dose, reproductive and developmental toxicity endpoints and a combined study is proposed to address all three endpoints. We agree that a combined study is warranted, as DMAA appears to be a relatively non-toxic chemical and the combined tests will save both animals and time.

4. The existing acute toxicity study was not conducted according to GLP and it is a fairly weak study. However, we agree with the sponsor that a new acute toxicity study would be of little value since DMAA appears to be relatively non-toxic and the range finding component of the combined study will generate data on any high-dose acute effects.

Thank you for this opportunity to comment.

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